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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/560,389	12/13/2005	J Michael Palmowski	0380-P03220US1	2535

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DANN, DORFMAN, HERRELL & SKILLMAN
1601 MARKET STREET
SUITE 2400
PHILADELPHIA, PA 19103-2307

EXAMINER	
BLUMEL, BENJAMIN P	

ART UNIT	PAPER NUMBER
1648	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/560,389	PALMOWSKI ET AL.	
	Examiner	Art Unit	
	BENJAMIN P. BLUMEL	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 June 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) *3-6,8,9,11,12 and 15-30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,7,10,13 and 14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12/13/05* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *June 27, 2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of group I in the reply filed on June 23, 2008 is acknowledged. The traversal is on the ground(s) that the European Patent Office Examiner that conducted the preliminary search of PCT/GB/04/02512, which this application is the national stage entry of, did not indicate any lack of unity. Therefore, the restriction requirement of January 22, 2008 fails to comply with the international rules with regard to following the prosecution of applications filed under §371. Furthermore, it is unclear how the examiner prosecuting the instant application can interpret the claims as being drawn to inventions when the PCT examiner, which employed the same rules, determined that the same claims have complete unity.

This is not found persuasive because the finding of lack of unity by the instant examiner is not dependent on any action taken by the PCT examiner. Furthermore, the kit of claim 19 requires that the lentiviral vector express the antigen in the targeted cell, whereas the method of claim 1 does not mention such a limitation. Moreover, the MPEP § 1893.03(d) states,

"When making a lack of unity of invention requirement, the examiner must (1) list the different groups of claims and (2) explain why each group lacks unity with each other group (i.e., why there is no single general inventive concept) specifically describing the unique special technical feature in each group.

The principles of unity of invention are used to determine the types of claimed subject matter and the combinations of claims to different categories of invention that are permitted to be included in a single international or national stage patent application. See

MPEP § 1850 for a detailed discussion of Unity of Invention. The basic principle is that an application should relate to only one invention or, if there is more than one invention, that applicant would have a right to include in a single application only those inventions which are so linked as to form a single general inventive concept.

A group of inventions is considered linked to form a single general inventive concept where there is a technical relationship among the inventions that involves at least one common or corresponding special technical feature. The expression special technical features is defined as meaning those technical features that define the contribution which each claimed invention, **considered as a whole, makes over the prior art**." Therefore, given the breadth of claims 1 and 19, their special technical feature do not make a contribution over the prior art of Tellier et al. (AIDS, 1998, page 13).

The requirement is still deemed proper and is therefore made FINAL.

Claims 3-6, 8, 9, 11, 12 and 15-30 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected species and invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on June 23, 2008.

Claims 1, 2, 7, 10, 13 and 14 are examined on the merits.

Information Disclosure Statement

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper."

Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

The information disclosure statement (IDS) submitted on June 27, 2008 was filed after the mailing date of the restriction/election requirement Office action on January 22, 2008. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. *See page 25.*

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 7, 10, 13 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by O'Neill et al. (Journal of Medical Primatology, 2002).

The claimed invention (claims 1, 2, 7 and 10) is drawn to a method of stimulating an immune response to an antigen in an individual by a heterologous prime-boost immunization protocol, the method comprising the steps of:

i) administering to the individual a plasmid or other expression vector, which encodes said antigen to prime said immune response;

ii) administering to the individual a lentivirus engineered to comprise nucleic acid encoding said antigen to boost the primed immune response.

The claimed invention (claims 13 and 14) also includes a method of administering lentivirus particles, which encode said antigen, to an individual in order to boost a pre-existing immune response that was elicited by the administration of a nucleic acid also encoding said antigen. However, for purposes of examination, this alternative method involving the boosting of a pre-existing immune response is interpreted to be within the same scope as that of the prime/boost method of claim 1.

O'Neill et al. teach a prime-boost method in which rhesus macaques received three intramuscular injections of plasmids encoding Simian Immunodeficiency Virus (SIV) proteins Gag, Rev, Env and Nef, followed by a boosting injection, subcutaneously, of SIVsmB7 virus-like particles (VLP). Nine weeks following the boost administration, the macaques where challenged by SIVemE660 virus, followed by analysis of antibody titers every couple of weeks. For each test group, an increase in anti-gp120 and anti-p-27 antibodies was observed after week 3-post challenge. Therefore, the results of O'Neill et al. show an immune response being generated to their heterologous prime-boost method and the claimed invention is anticipated. *See pages 218 and 219 and figures 2 and 3.*

Claims 1, 2, 7, 10, 13 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Rovinski et al. (US PGPub 2002/0051770 A1).

The claimed invention (claims 1, 2, 7 and 10) is drawn to a method of stimulating an immune response to an antigen in an individual by a heterologous prime-boost immunization protocol, the method comprising the steps of:

i) administering to the individual a plasmid or other expression vector, which encodes said antigen to prime said immune response;

ii) administering to the individual a lentivirus engineered to comprise nucleic acid encoding said antigen to boost the primed immune response.

The claimed invention (claims 13 and 14) also includes a method of administering lentivirus particles, which encode said antigen, to an individual in order to boost a pre-existing immune response that was elicited by the administration of a nucleic acid also encoding said antigen. However, for purposes of examination, this alternative method involving the boosting of a pre-existing immune response is interpreted to be within the same scope as that of the prime/boost method of claim 1.

Rovinski et al. teach a prime-boost method of inducing an antibody response to HIV antigens, particularly the envelop glycoprotein. In order to induce such an immune response, Rovinski et al. teach to prime with plasmids encoding the envelop glycoprotein, and then boost with non-infectious, non-replicating HIV-like particles that encode this envelope glycoprotein. Therefore, Rovinski et al. anticipate the claimed invention. *See abstract and paragraphs [5, 10, 11, 20, 40 and 41].*

Summary

No claims are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BENJAMIN P. BLUMEL whose telephone number is (571)272-4960. The examiner can normally be reached on M-F, 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-1600. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Stacy B Chen/
Primary Examiner, Art Unit 1648

/BENJAMIN P BLUMEL/
Examiner
Art Unit 1648